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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,875	09/26/2001	Joel F. Habener	17633/1235	9674

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EXAMINER
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BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/02/2003

131

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/963,875

Applicant(s)

HABENER ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-74 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Applicant's amendment, filed 12/21/01 (paper No: 5) is acknowledged.

*Claims 1-74 are pending.*

### ***Restriction Requirement***

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-9, drawn to a method of treating a patient with diabetes mellitus, comprising the step of isolating a nestin-positive pancreatic stem cells, classified in Class 424, subclass 577.
  - II. Claims 10-18, drawn to a method of treating a patient with diabetes mellitus, comprising the step of expanding the stem cell *ex-vivo* to produce a progenitor cell, classified in Class 424, subclass 577 and Class 435 subclass 375.
  - III. Claims 19-27, drawn to a method of treating a patient with diabetes mellitus, comprising the step of differentiating the progenitor cell in culture to form pseudo-islet like aggregates, classified in Class 424, subclass 577 and Class 435 subclass 375.
  - IV. Claims 28-33, drawn to a method of isolating a stem cell from a pancreatic islet of Langerhans, classified in Class 435, subclasses 375 and 383.
  - V. Claims 34-38, drawn to a method of inducing the differentiation of a nestin-positive pancreatic stem cell, classified in Class 435, subclasses 375 and 383.
  - VI. Claims 39-42, 43, and 74 drawn to an isolated, nestin-positive human pancreatic or liver stem cell that differentiates to form insulin-producing beta cell and a pharmaceutical composition comprising said cells, classified in Class 435, subclass 372.
  - VII. Claims 39-42, 44 and 74, drawn to an isolated, nestin-positive human pancreatic or liver stem cell that differentiates to form glucagons-producing alpha cells and a pharmaceutical composition comprising said cells, , classified in Class 435, subclass 372.

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- VIII. Claims 39-42 , 45 and 74 drawn to an isolated, nestin-positive human pancreatic or liver stem cell that differentiates to form pseudo-islet like aggregates and a pharmaceutical composition comprising said cells, classified in Class 435, subclass 372.
- IX. Claims 39-42 , 46 and 74, drawn to an isolated, nestin-positive human pancreatic or liver stem cell that differentiates to form hepatocytes and a pharmaceutical composition comprising said cells , classified in Class 435, subclass 372.
- X. Claims 39-42, 47 and 74, drawn to an isolated, nestin-positive human pancreatic or liver stem cell that does not express class I MHC antigens and a pharmaceutical composition comprising said cells , classified in Class 435, subclass 372.
- XI. Claims 48- 53, drawn to a method of identifying a pancreatic cells as a stem cell, classified in Class 435, subclasses 366, 373 and 375.
- XII. Claims 54-58, drawn to a method of inducing a nestin-positive pancreatic stem cell to differentiate into hepatocytes, classified in Class 435, subclass 377.
- XIII. Claims 59-63, drawn to a method of treating a patient with liver disease, comprising the step of isolating a nestin-positive pancreatic stem cells, classified in Class 424, subclass 577
- XIV. Claims 64-68, drawn to a method of treating a patient with liver disease, comprising the step of expanding the stem cell *ex-vivo* to produce a progenitor cell, classified in Class 424, subclass 577 and Class 435 subclass 377.
- XV. Claims 69-73, drawn to a method of treating a patient with liver disease, comprising the step of expanding the stem cell *ex-vivo* to produce a hepatocyte , classified in Class 424, subclass 577 and Class 435 subclass 377.

3. Groups I-V and XI - XV are different methods. These invention are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

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4. Groups VI-X are different products. These inventions are different with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

### **Species Election**

6. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If one of the Groups I, II, III is elected, applicant is required to elect a specific method of treating a patient with diabetes mellitus, wherein the stem cell is treated ex vivo with specific agent selected from the group recited in claims 6, 15, 24 and wherein a specific immunosuppressive agent is selected from the group, recited in claim 9, 18, 27.

These species are distinct because a specific method of treating a patient with diabetes mellitus, wherein the stem cell is treated ex vivo with specific agent selected from the group recited in claim 6 and wherein a specific immunosuppressive agent is selected from the group, recited in claim 9 differ with respect to the specific agent and the endpoint of the method; thus each specific method employing a specific agent represents patentably distinct subject matter.

Furthermore, the examination of specific agent selected from the group recited in claim 6, 15, 24 and specific immunosuppressive agent from the group, recited in claim 9, 18, 27 would require different searches in the scientific literature.

B. If Group IV is elected, applicant is required to elect a specific method of isolating a stem cell from a pancreatic islet of Langerhans, wherein the nestin-positive clone is treated ex vivo with specific agent selected from the group recited in claim 33.

These species are distinct because a specific method of isolating a stem cell from a pancreatic islet of Langerhans, wherein the nestin-positive clone is treated ex vivo with specific agent

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selected from the group recited in claim 33 differ with respect to the specific agent and the endpoint of the method; thus each specific method employing a specific agent represents patentably distinct subject matter. Furthermore, the examination of specific agent selected from the group recited in claim 33 would require different searches in the scientific literature.

C. If Group V is elected, applicant is required to elect a specific method of inducing the differentiation of a nestin-positive pancreatic stem cell, wherein nestin-positive or GLP-1R positive cells are treated with a specific agent selected from the group recited in claims 34 and 36.

These species are distinct because a specific method of inducing the differentiation of a nestin-positive pancreatic stem cell, wherein nestin-positive or GLP-1R positive cells are treated with a specific agent selected from the group recited in claims 34 and 36 differ with respect to the specific agent and the endpoint of the method; thus each specific method employing a specific agent represents patentably distinct subject matter. Furthermore, the examination of specific agent selected from the group recited in claims 34 and 36 would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).


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8. A telephone call was made to Kathleen M. Williams on 6/25/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.  
Patent Examiner  
June 26, 2003.

  
CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
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